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Trial Affidavit of Meredith Rosenthal

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: ALL ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

DIRECT TESTIMONY OF DR. MEREDITH ROSENTHAL

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I. INTRODUCTION

1. I have been retained by Counsel to the Classes of consumers and third-party payers who paid for drugs based on AWP and for which that AWP was inflated (AWPIDs). The three Classes certified by Judge Saris and addressed in my work are: (1) the nationwide Class of Medicare Part B beneficiaries, (2) the Massachusetts class of third-party payers (TPPs) that pay Medicare supplemental insurance, and (3) the Massachusetts class of TPPs and consumers paying for physician-administered drugs outside of Medicare. I have investigated:

- the economic incentives for manufacturers to inflate AWPs and for health care providers to select therapies with inflated AWPs,
- empirical clues in the invoice data supplied by the Defendants that suggest AWP inflation, and in particular, whether the data support the theory that the Defendants used the spread between AWP and their net sales price to providers as a competitive device, and
- whether the Classes would likely have been economically injured by the alleged AWP inflation.

2. I conclude that the unlawful conduct alleged in the Amended Complaint regarding AWP inflation of physician-administered and other Medicare Part B-reimbursable drugs has occurred and has resulted in economic harm to the Classes. I find that there were strong economic incentives for the Defendants to have engaged in the allegedly unlawful AWP inflation. These incentives, coupled with the general lack of price transparency in the market for the drugs in question, created an environment in which AWP inflation would be economically rational behavior for a pharmaceutical manufacturer. Moreover, my analysis of manufacturer invoice data demonstrates pricing patterns, including price changes in response to changes in the

competitive environment, that are consistent with the allegations. Finally, because their payments to providers for the AWPIDs were a mathematical function of the AWPs, members of the three Classes would have been economically injured if the Defendants inflated those AWPs as alleged.

3. To arrive at these opinions, I have appealed to theory, data, and methods generally relied upon by experts in my field and I have appropriately applied standard approaches and analyses. The scientific bases for my conclusions are described in my testimony. Because my findings relate to and build upon my December 2004 tutorial report to the Court on this matter, I incorporate that document by reference as well.[1]

II. QUALIFICATIONS

4. My name is Meredith Rosenthal. I am an Associate Professor of Health Economics and Policy at the Harvard School of Public Health and an Academic Affiliate of Greylock McKinnon Associates (GMA), a consulting and litigation support firm. My principal research interests concern the economics of the health care industry including pharmaceuticals.

5. At Harvard, I have taught in Masters'-level and Ph.D.-level health economics courses and lectured on a variety of health policy issues. Since 1996, I have worked with GMA on a number of matters, most of which relate to litigation in health care markets generally and the pharmaceutical industry in particular. I have submitted written and presented oral testimony in an earlier phase of this litigation. I have submitted written and presented oral testimony in litigation regarding the physician administered drug Lupron;[2] I have submitted written testimony

[1] "Written Tutorial of Dr. Meredith Rosenthal," *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS ("*Rosenthal Tutorial*").

[2] *In re Lupron Marketing and Sales Practices Litig.*, United States District Court, District of Massachusetts, MDL No. 1430, CA No. 01-CV-10861.

in litigation regarding the drugs Augmentin and Neurontin.[3] Working with a team of health care experts, I submitted written testimony assessing and measuring the impacts of smoking on Medicaid health care costs in the Commonwealth of Massachusetts. In addition, I have consulted to GMA in a broader array of markets, including other pharmaceutical matters such as litigation related to the following drug products: Buspar, Cardizem CD, Cipro, Hytrin, K-Dur, lorazepam and clorazepate, Relafen, Taxol and Wellbutrin SR.[4]

6. I have conducted research on a wide variety of health economics topics, with a focus on the financing and organization of the U.S. health care system. A number of these studies relate to prescription drugs. Specific topics I have studied include the design of a Medicare prescription drug benefit[5] and direct-to-consumer advertising of prescription drugs.[6]

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[3] *In re Augmentin Antitrust Litigation*, United States District Court for the Eastern District of Virginia, No. 02-CV-442; *In re: Neurontin Marketing and Sales Practices Litigation*, MDL Docket No. 1629, Master File No. 04-10981, United States District Court, District of Massachusetts; and *Gregory Clark and Linda Meashey, individually and on behalf of others similarly situated v. Pfizer Inc., and Warner-Lambert Company, LLC*, No. 01819, Philadelphia County Court of Common Pleas..

[4] *In re Buspirone Antitrust Litigation*, MDL No. 1413, United States District Court for the Southern District of New York; *In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation*, Docket No. 9293, United States of America Before Federal Trade Commission; *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York; *In re Terazosin Hydrochloride Antitrust Litigation*, Case No. 99-MDL-1317 Seitz/Garber, United States District Court for the Southern District of Florida; *In re K-Dur Antitrust Litigation*, Civil Action No. 01-1652 (JAG), (Consolidated Cases), MDL No. 1419, United States District Court for the District of New Jersey; *In re Lorazepam and Clorazepate Antitrust Litigation*, MDL No. 1290, United States District Court for the District of Columbia; *In re Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY; *HIP Health Plan of Florida, Inc., on Behalf of Itself and All Others Similarly Situated v. Bristol-Myers Squibb Co. and American Bioscience*, Case Number 1:01CV01295, United States District Court for the District of Columbia; *IBEW - NECA Local 505 Health & Welfare Plan and Joanne C. Gaddy v. SmithKline Beecham Corporation, and GlaxoSmithKline, PLC*, United States District Court for the Eastern District of Pennsylvania.

[5] H.A. Huskamp, M.B. Rosenthal, R.G. Frank, and J.P. Newhouse, "The Medicare Prescription Drug Benefit: How Will the Game Be Played?" *Health Affairs*, 19(2): 8-23, March/April 2000.

[6] M.B. Rosenthal, E.R. Berndt, R.G. Frank, J.M. Donohue and A.M. Epstein, "Promotion of Prescription Drugs to Consumers," *New England Journal of Medicine*, 346(7):498-505, Feb. 2002; M.B. Rosenthal, E.R. Berndt, J.M. Donohue, A.M Epstein, R.G. Frank, "Demand Effects of Recent Changes in Prescription Drug Promotion," *Frontiers in Health Policy Research*, v. 6, David M. Cutler and Alan M. Garber, editors, MIT Press, June 2003; M. Mello, M.B. Rosenthal, P.J. Neumann, "Direct-to-Consumer Advertising and Shared Liability for Pharmaceutical Manufacturers," *JAMA*, 289(4): 477-81, Jan. 22, 2003; J.M. Donohue, E.R. Berndt, M.B. Rosenthal, A.M. Epstein, R.G. Frank, "Effects of Pharmaceutical Promotion on Adherence to Guideline Treatment of Depression," *Medical Care*, 2004.

Presently, I am engaged in a large-scale evaluation of the effects of prescription drug formularies on drug choice and health care spending. I have published numerous peer-reviewed journal articles, essays, and book chapters.

7. I received an A.B. in International Relations from Brown University in 1990 and a Ph.D. in Health Policy (Economics Track) from Harvard University in 1998. A more complete description of my qualifications is found in my *Curriculum Vitae*, which is included as Attachment A to this report.

8. In preparing this report, I reviewed a wide variety of documents produced by the Defendants in this case including strategic memoranda and contracts, related legal filings, reports, and both scientific and industry publications related to pharmaceutical distribution and reimbursement. These sources are listed in Attachment B to this report. I have also examined the drug transaction and pricing data that are summarized in Dr. Hartman's December 15, 2005 Liability and Damages Report.[7] I also rely on my training, research, and experience as an economist on matters relating to health economics.

III. BACKGROUND, SUMMARY OF ALLEGATIONS AND SUMMARY OF MY CONCLUSIONS

9. I have been retained by Counsel to the Class of consumers and third-party payers who paid for drugs based on AWP and for which that AWP was inflated (hereafter, these drugs will be referred to as AWP-inflated drugs or AWPIDs). The allegations in this matter are summarized in the Amended Master Consolidated Complaint[8] and pertain to the physician-

[7] "Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages," *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS, December 15, 2005.

[8] Amended Master Consolidated Class Action Complaint, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS.

administered, AWPIDs of five manufacturers: AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, and Schering Plough. I have been instructed by Counsel that GlaxoSmithKline has settled and is no longer party to this litigation. It is my understanding that Judge Saris identified a subset of the proposed Class and in particular identified the following three Classes for ongoing litigation:

- Class 1: "[N]ationwide class of Medicare Part B beneficiaries;"
- Class 2: Massachusetts statewide "class of TPPs that pay MediGap supplemental insurance to cover Medicare co-payments;" and
- Class 3: Massachusetts statewide class of "TPPs and consumers paying for physician-administered drugs in the private context based on AWP … for brand-name drugs and those generic drugs for which reimbursement was explicitly based on AWP, not MAC pricing."[9]

Further, I understand that this testimony is directed specifically to Classes 2 and 3.

10. In my testimony below I describe the economic theory and evidence that support the conclusion that the alleged practices of Defendants caused harm to the Classes defined by Judge Saris. To do so, I have analyzed the economic circumstances and incentives that have made the alleged fraud possible and profitable. This analysis relies upon a standard economic characterization of key institutions in the U.S. health care industry including the role of insurance in paying for the drugs at issue, the nature of competition in both the pharmaceutical and provider markets, and the central role of AWP as a pricing benchmark for pharmaceuticals. Further, using standard empirical methods applied to the manufacturer transaction and price data,

[9] *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Memorandum and Order re: Motion for Class Certification, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, August 16, 2005, pp. 87-88 ("*Memorandum and Order*").

I examine whether the Defendants' market behavior is consistent with the allegations of AWP inflation. Where appropriate, I support my economic analysis with the Defendants' own statements as obtained through deposition and discovery as well as data analysis for the drugs in question.

11. My analysis leads to the following conclusions:

- AWP is the most widely used pricing benchmark in the industry. During the Class Period, AWP or a discount off of AWP was the basis for Medicare reimbursement for brand name drugs covered under Part B. Likewise, multi-source drugs were reimbursed under Medicare based on the median AWP for generic versions or the lowest brand-name AWP. Most private insurers have followed Medicare's lead and also reimburse for physician-administered drugs using a discount off of AWP, with AWP being the pricing benchmark in the non-Medicare market.
- The system of third-party reimbursement and the large number of drugs, procedures, and other services covered by health insurers combined with the opaque discounting practices of the Defendants presented an opportunity for the alleged unlawful conduct to have occurred.
- Physicians and other providers of the drugs at issue in this matter could increase their net revenues (i.e., reimbursement net of the acquisition costs of the drugs) under this system by selecting drugs with larger spreads – *i.e.*, drugs where the AWP was inflated in relation to the acquisition cost of the drug.
- Manufacturers, in turn, could increase their unit sales not only by discounting their products, but also by raising their reported AWPs. Moreover, raising the AWP would be the more profitable strategy in that it could be expected to increase the number of

units sold, but would have no negative impact on the manufacturers' profit margins. Therefore, spreads can be created and/or maintained by either lowering ASP while maintaining AWPs or by increasing AWPs.

- Because their payments to providers for the AWPIDs were a mathematical function of the AWPs, members of Classes 2 and 3 would have been economically injured if the Defendants inflated or maintained those AWPs as alleged. That is, members of the Classes paid more for these drugs than they would have in the absence of the alleged unlawful conduct.

IV. OVERVIEW OF THE DRUGS AT ISSUE

12. For the purposes of my testimony, I focus on the allegations of AWP inflation with respect to the set of drugs listed in Table 1 below.

13. The majority of AWPIDs that are the subject of this report are referred to as "physician-administered" because they are typically delivered in a physician's office through injection or infusion. Also included in this group are drugs that are nebulized (reduced to a fine spray or vapor) and may be delivered either in an outpatient clinic or at the patient's home using durable medical equipment (DME). These nebulized drugs are included in this matter because they are covered under Medicare Part B. In addition, Table 1 lists several self-administered drugs used for cancer treatment that are also covered under Medicare Part B including Temodar and Cytoxan tablets.

Table 1
Track One Defendants: Drugs

Manufacturer	***Drug Name***
AstraZeneca	Zoladex
Bristol-Myers Squibb	Blenoxane Cytoxan Etopophos Paraplatin Rubex Taxol Vepesid
Johnson & Johnson	Procrit Remicade
Schering-Plough, Warrick	Albuterol Intron A Perphenazine Proventil Temodar

14. Many of the drugs in Table 1 fall into the category of specialty pharmaceuticals, which includes a number of very expensive biologic pharmaceuticals as well as chemotherapeutic agents. Let me describe a few of the leading therapies among the Class drugs:[10]

- Zoladex, manufactured by AstraZeneca, is an injectable drug that is used principally to treat prostate cancer. During the Class Period, the AWP of a one-month dose of Zoladex ranged from roughly $320 to more than $450. Typically patients would be on Zoladex for more than one month.
- Taxol, manufactured by Bristol-Myers Squibb, is a treatment for ovarian and breast cancer as well as AIDS-related Kaposi's sarcoma. For a typical dose for adjuvant

[10] All references to drug "costs" are based on the published AWP according to the Red Book. Dosing information was taken from the FDA-approved prescribing information produced by the respective companies.

therapy for breast cancer (assuming body weight of 150 pounds and height 5'6" = 1.78 square meters of surface area), the AWP for Taxol is more than $1,800.

- Remicade, a Johnson & Johnson product, is a biologic injectable that is indicated for Crohn's disease and rheumatoid arthritis among other conditions. Evaluated at the AWP, the recommended dosage (3 mg/kg of body weight every 8 weeks) of Remicade for a typical patient (150 pounds) with rheumatoid arthritis would be more than $1000 (per dose, which is indicated every 8 weeks) during the Class Period.
- Intron A, manufactured by Schering-Plough, is an injectable therapy for melanoma, leukemia, hepatitis and several other life-threatening conditions. For maintenance therapy of malignant melanoma, the recommended dosage of Intron A is 10 million IU three times per week. At the AWP, this quantity would have cost nearly $500 per week in 2004, and a typical patient would be on this drug for more than one week.

V. MEDICARE PART B

15. As was described more fully in my tutorial,[11] the Medicare program is comprised of several distinct parts: Part A covers hospital services, Part B covers professional services, Part C is Medicare managed care (now called "Medicare Advantage"), and Part D is the prescription drug benefit that took effect on January 1, 2006. During the Class Period, under Part B, Medicare generally covered only those drugs that were "incident to" a physician's service, drugs administered with durable medical equipment (DME), and drugs specifically covered by statute (for example, oral immunosuppressive drugs). Covered drugs also include

[11] *See Rosenthal Tutorial.*

some self-administered forms of drugs that are primarily physician-administered, such as the anti-emetic drugs.[12]

16. To get a sense of what these Medicare Part B drugs are like, let me describe the leading drugs in this category in the mid-1990s (all of which continue to be important therapies).

Part B Drug Rank in 1995 Expenditures	**Drug is Used For**
1. Lupron	Prostate Cancer
2. Albuterol	Asthma
3. Taxol	Breast, ovary and lung cancer

Lupron and Taxol are agents that are used to treat some of the most prevalent cancers among the Medicare population. Albuterol is a very common asthma drug; Medicare only covers it when it is administered by nebulizer (a machine that administers a course of treatment through a mask). Patients with moderate or severe asthma, emphysema, or chronic obstructive pulmonary disease (a serious respiratory condition) are administered such treatment to relieve bronchospasms. Thus, Albuterol accounts for a big share of Medicare Part B expenditures in part because the chronically ill people who require the medication use it repeatedly.

17. For a Medicare Part B covered drug, like all professional services, generally 80% of the cost is paid for by the federal government, and 20% is paid for by whomever is responsible for the co-payment. For example, an individual Medicare recipient may have a private supplemental insurance policy that covers their coinsurance and deductibles. In Massachusetts, these third-party payers are members of Class 2. There are more than four million Medicare enrollees in the United States who do not have supplemental insurance

[12] Currently, those drugs that "are not usually self-administered by the patient" are covered under Medicare Part B. *See* § 112 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act ("BIPA").

coverage and must pay their own coinsurance for Part B.[13] These individuals are represented in Class 1. Even for those persons who have some form of supplemental coverage for the Medicare coinsurance, features of that coverage (*e.g.*, coinsurance on the coinsurance) may well result in the individual becoming obligated to pay some portion of the coinsurance. For example, employer-sponsored supplemental plans, which cover about a third of the Medicare population or 13 million people, typically require enrollees to pay 20% of the 20%.[14] Individuals with this type of supplemental plan will also be in Class 1.

1. Reimbursement of Drugs Under Medicare Part B

18. Reimbursement for prescription drugs under Part B in the Medicare program has been based on the Average Wholesale Price (AWP)[15,16] reported by drug manufacturers and published in the standard directories (Red Book, First Databank (Blue Book) and MediSpan). While the precise formula for AWP-based reimbursement has changed over time, reliance on AWP has been a constant.

19. Prior to January 1, 1998, Medicare carriers were to determine the allowed amount for a covered drug based on the lower of the Estimated Acquisition Cost ("EAC") or 100% of the

[13] *See* Distribution of Supplementary Insurance for the Medicare Population as presented in *Rosenthal Tutorial* and which cites Franklin Eppig and George Chulis, "Trends in Medicare Supplementary Insurance: 1992-1996," *Health Care Financing Review*, 19 (1), Fall 1997, Table 1, p. 202.

[14] National Bipartsan Commission on the Future of Medicare, http://medicare.commission.gov/medicare/K-P-1499.html as accessed October 2006.

[15] "Apparently from the beginning of the program, Medicare has based payment for drugs on published 'average wholesale price' (AWP). AWP is used throughout public and private insurance programs as the basis for drug reimbursement, both for drugs administered in physician offices and for drugs dispensed by pharmacies. The amount of reimbursement varies from plan to plan and setting to setting, but it is almost always expressed as a percentage of AWP." American Society of Clinical Oncology (ASCO), *Reform of the Medicare Payment Methods for Cancer Chemotherapy*, May 2001, p. 5.

[16] Medicare currently pays 106% of ASP for drugs administered in a physician's office (Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 352, November 3, 2004); in 2004, Medicare generally paid 85% of AWP with selected drugs ranging from 80-95% of AWP (Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 54, December 24, 2003); between 1998 and 2004 the amount was 95% of AWP (42 CFR 405.517, Revised October 1, 2003).

national AWP for that drug. The EAC was to be determined based on a survey of actual invoice prices paid for the drug and thus designed to represent the actual cost (or "usual and customary charges") of drugs for direct purchasers (the providers, in the case of Medicare Part B).

20. Historically, however, Medicare carriers have not conducted such surveys and have based reimbursement on AWP.[17] Furthermore, on January 1, 1998, 42 C.F.R. § 405.517 was amended so that the allowed amount would be based on the lower of the billed charge or 95% of AWP. In practice, this has meant that the majority of reimbursement has been undertaken using the AWP.

21. An AstraZeneca document succinctly explains reimbursement in the Medicare Part B market:

> "How is Medicare Part B reimbursed? Office based physicians can choose to participate or not in Medicare. As a participator, the physician agrees to accept the fee schedule Medicare establishes. Essentially, the physician files a claim; Medicare pays for 80% of the claim and the patient is responsible for the remaining 20%. Some patients may have a secondary insurance which will pay 80% of the 20% co-pay. This leaves 20% of the 20% (4%) that the patient is responsible for."[18]

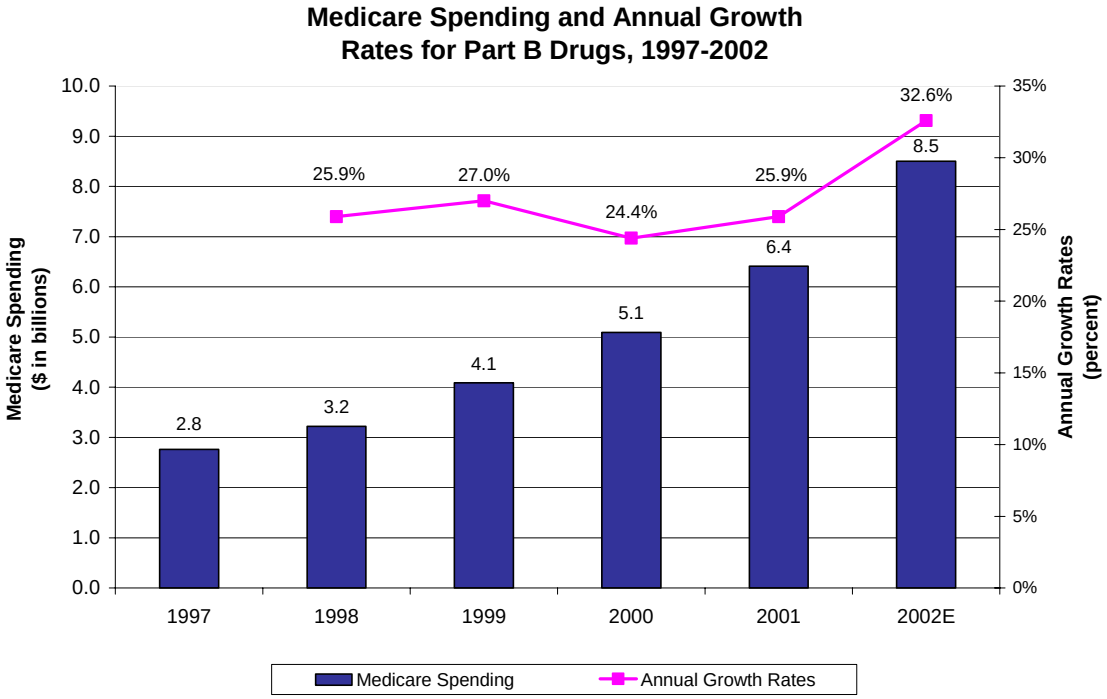
22. As with other sectors, there has been rapid growth in Medicare Part B drug expenditures:

> "Analysis of the sources of this growth reveals that only a few of the approximately 450 covered drugs account for most of the spending. [Part B] drug expenditures in 1998 were about $3.3 billion and this amount grew to more than $8.4 billion by 2002. During the same period (1998 to 2002), Medicare enrollment grew only 1.4 percent per year while the drug spending grew an average of 27 percent per year. The vast majority (77%) of the Medicare Part B drug expense is paid to oncologists and urologists. Oncologist-based drug expenditures grew from $1.2 billion in 1998 to $3.8 billion in 2002 with the spending growth from 2001 to 2002 at 41 percent. The spending on drugs under

[17] *See* "Excessive Medicare Payments for Prescription Drugs," Office of Inspector General, Department of Health and Human Services, December 1997, OEI-03-97-00290, pp. i-iii.

[18] Plaintiffs' Exhibit 15, email with attachment titled "Medicare Review" from M. Hammons, October 19, 2000, AZ0431807-811 at AZ0431808 (emphasis in original).

Medicare Part B is highly concentrated with 7 of the approximately 450 drugs accounting for 49 percent of the spending ($4.0 billion out of $8.4 billion). Nineteen drugs accounted for 75 percent of the total drug spend [*sic*] and 33 drugs accounted for 86 percent of the total. Both drug product price increases at the manufacturer level and increases in utilization appear to have been the major contributors to growth in drug expenditures for the Medicare Part B program."[19]



Source: MedPAC Report to Congress, "Variation and Innovation in Medicare," June 2003, p. 154, Figure 9-2.

VI. COVERAGE AND REIMBURSEMENT FOR PHYSICIAN-ADMINISTERED DRUGS FOR CONSUMERS NOT ENROLLED IN MEDICARE

23. Class 3 includes third-party payers and individuals in Massachusetts that paid for physician-administered drugs outside of the Medicare context. In Massachusetts, approximately

[19] S. W. Schondelmeyer and M. V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates Inc., June 2004, pp. 8-9 (footnote to DHHS, Center for Medicare and Medicaid Services, "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule," Federal Register, Aug. 20, 2003, 50428-52, has been omitted).

4 million individuals were covered by private insurance plans in 2003[20] and thus are potentially in this Class.

24. Because the drugs that are the subject of the ongoing litigation are for the most part very expensive and associated with ongoing treatment of very high-cost conditions, I expect, and Dr. Hartman's analysis suggests,[21] that very few individuals pay for the drugs in question entirely out-of-pocket. In previous work examining the insurance coverage for individuals receiving Lupron, an injectable drug that treats prostate cancer, the National Ambulatory Medical Care Survey indicated that none of these patients were "self-pay" (uninsured).

25. Individuals with private health insurance typically receive coverage for prescription drugs administered by a clinician under their medical benefit. For the purposes of understanding the extent to which consumers with private insurance coverage were directly impacted by the alleged AWP inflation it is important to note that many consumers pay flat office visit copayments under their medical benefits. Nonetheless, about 10% of the population with employer-sponsored coverage pays coinsurance for a physician's office visit and the typical coinsurance rate is 20 to 25%.[22]

26. Private health insurance reimbursement of physician-administered drugs resembles the Medicare Part B reimbursement approach described above. The Medicare Payment Advisory Commission (MedPAC) contracted with Dyckman & Associates in 2002 to conduct a survey of private health plans regarding their payments for physician-administered drugs. That survey found that "[a]ll of the plans use a percentage of AWP" as a formula to

[20] Kaiser Family Foundation, State Health Facts, *Health Insurance Coverage of Nonelderly 0-64, states (2003-2004), U.S. (2004)* (http://www.statehealthfacts.org accessed 12/13/05).

[21] *See* Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005, *op. cit.*

[22] 2004 Annual Survey of Employer Health Benefits conducted by the Kaiser Family Foundation and the Health Research and Educational Trust, p. 98.

reimburse physicians for these drugs.[23] The study found that "most plans use an AWP pricing formula that is in the range of 90 to 100 percent of AWP. The average percent of AWP used by the plans is 98 percent."

27. My review of the reimbursement landscape here and in my earlier tutorial[24] points to a natural conclusion: Class members overwhelmingly paid for the drugs at issue based on the published AWPs. If those AWPs were inflated, then the Classes would have paid more for the drugs than if the AWPs were based on industry standard mark-ups. I understand that the Court may use a "plain meaning" approach to Class 2 in which case Class 2 would have overpaid in those cases where the published AWPs exceeded the true average prices.

VII. INCENTIVES FOR PROVIDERS IN THE CONTEXT OF MARKET FAILURE: WHY COMPETITION IS UNLIKELY TO DISSIPATE THE EFFECTS OF INFLATED AWPS

28. Most economic models of physician behavior are based on the notion that physicians choose therapies in part based on the impact of these choices on their net revenues.[25] When it comes to the drugs described in Table 1, physician net revenues are equal to the difference between AWP less an agreed-upon discount and the acquisition cost of a drug. This difference has been called the "spread," "margin," or "return to practice." Thus, all else equal, physicians will have an incentive to select a product with a larger spread, even if the acquisition cost of that drug exceeds that of a therapeutic substitute.

[23] Health Plan Payment for Physician-Administered Drugs, a study conducted by Dyckman & Associates for the Medicare Payment Advisory Commission, August 2003, p. 3.

[24] *See Rosenthal Tutorial*, pp. 4-7 and 9-10.

[25] Thomas G. McGuire, "Physician Agency" in *Handbook of Health Economics*, eds. A.J. Culyer and J. P. Newhouse, Volume 1A, pp. 463-536, Elsevier, Amsterdam, 2000.

29. Defendants' economists have suggested that competition among the providers of pharmaceuticals will dissipate any possible impact of AWP inflation.[26] Specifically, they imply that payers will simply negotiate larger discounts in their physician contracts to account for higher spreads. But it is well known among health economists that medical care markets suffer from numerous market failures and are characterized by a wide variety of institutional features that serve to dampen price competition.[27]

30. Under Medicare Part B and private insurance, the suppliers purported to compete vigorously on the basis of price are typically specialty physicians. As professionals, physicians command a large amount of technical and clinical information that is not accessible to patients or payers who can only imperfectly judge whether a physician is making appropriate diagnoses or treatment choices. Such asymmetric information about the nature of the service being delivered poses problems for price competition because patients and payers are unable to make "apples to apples" comparisons of providers – that is, to compare prices for services of equal value. This asymmetry of information, along with the high stakes involved (health), also leads to the importance of trust in physician-patient interactions. Trust, in turn, limits the substitutability of physicians from a given patient's perspective. This perceived differentiation of physicians on the basis of trust weakens price competition, particularly when the patients concerned are acutely or chronically ill as are most recipients of the physician-administered drugs now at issue. In the Medicare context, "negotiations" over price take the form of congressional action in an

[26] *See* Declaration of Eric M. Gaier, PhD. in Support of Defendants' Opposition to Class Certification, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS, October 25, 2004, ¶¶ 31-32.

[27] A seminal paper by Nobel laureate Kenneth Arrow in 1963 examines these issues and forms the basis for modern health economics (*see* K. J. Arrow, "Uncertainty and the Welfare Economics of Medical Care," *American Economic Review* 53(5):941-973).

environment of intense lobbying by specialty societies but have a largely similar outcome to the private process.

31. In other markets, economists look to free entry as a prerequisite to competition; barriers to entry allow current market participants to enjoy excess profits. But of course in the United States, entry into the market for physician services is constrained by limits on medical school capacity, limits on the numbers of foreign medical school graduates who may come to the United States as residents, medical licensing requirements, and specialty board exams among other factors. These barriers to entry are even greater for specialist physicians, whose residency and board certification requirements are typically much greater than those for primary care physicians.

32. In addition to looking at market structure, economists often look at the performance of an industry to judge competitiveness. As a key example for this case, consider the profitability of oncology practices. Oncologists administer a large share of the physician-administered drugs that are the subject of the allegations including Taxol, Cytoxan, Blenoxane, Etopophos and Procrit. Indeed, according to Professor Berndt's report, hematologist-oncologists, oncologists, and urologists (largely treating prostate cancer) accounted for more than 50% of Medicare Part B drug reimbursements in 2001.[28] According to the Medical Group Management Association, the top quartile of medical oncologists made upwards of $479,000 in 2001.[29] Furthermore, two thirds of the income of practice-based medical oncologists (those

[28] Ernst Berndt, "Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris," *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS, February 9, 2005 ("*Berndt Report*"), page 48.

[29] Physician Oncology Report, "Medical Oncology at a Glance," April 2003 (available at Atlantic Information Services, http://www.findarticles.com/p/articles/mi_m0FBW/is_4_4/ai_99824347, as accessed October 2006).

earning the most) comes from the mark-up on injectable drugs.[30] These figures suggest that competition has far from driven out excess profits associated with inflated AWPs.

VIII. THE ECONOMIC INCENTIVES FOR PHARMACEUTICAL MANUFACTURERS

33. Because physicians are the key decision makers for most therapies including those that are the subject of the allegations in this matter, pharmaceutical manufacturers compete for market share by positioning their products favorably from the physician's point of view. Such competition will occur along the non-financial dimensions of a product – the clinical attributes, side effect profile, how these aspects are promoted to physicians, and how intensively they are promoted – as well as the financial implications of a product choice. In the case of the Class drugs, the relevant measure of the financial consequence of choosing a particular physician-administered drug is the difference between the reimbursement for the drug, which is a function of AWP, and the acquisition cost of the drug to the physician or clinic. This means, as is true in other markets, that manufacturers can increase their market share by reducing the cost of their product to physicians through discounts or rebates. But the unique and perverse feature of this market is that pharmaceutical manufacturers can also increase market share through raising their AWP, since this list price is the basis for third-party reimbursement. Unlike offering big discounts to physicians, raising the AWP relative to the acquisition cost to the physician does not reduce profit margins on the drug in question.

34. An example of the economic incentives created by the spread is contained in the BMS document entitled, "Taxane Economics" which again highlights the "margins" created for physicians by virtue of the AWP-acquisition cost disparity.[31]

[30] Tom Reynolds, "Salary a Major Factor for Academic Oncologists, Study Shows," *Journal of the National Cancer Institute*, Vol. 93, No. 7, p. 491, April 4, 2001.

35. A document produced by AstraZeneca has a blunt reference to this incentive:

> "The market we are in wants a more expensive Zoladex, because the doctor can make more money."[32]

36. Although GSK is no longer a party to this litigation, their documents are enlightening on this subject. For example, a Glaxo document regarding an upcoming 3.5% increase on the Zofran injectables reads:

> "… in the interest of cost containment Glaxo would like to provide an option to your all-important clinic customers. Your clinic customers may avoid this price increase by signing a contract with Glaxo. … These agreements offer two substantial benefits to our customers who desire to participate. First is a reduction in the price of a product they use on virtually every patient receiving emetogenic cancer chemotherapy, and secondly, a higher AWP for reimbursement purposes, increasing the profitability of this high-volume product."[33]

37. An AstraZeneca document sums this motivation up as follows with respect to the sale of Zoladex: "As we have come to understand in our experience with ZOLADEX, Urologists are motivated by economics." "ZOLADEX has learned that in order to compete in [a] market dominated by Medicare, there needs to be a compelling argument based on 'total return to practice'."[34]

38. A J&J document regarding Procrit identifies a "RED ALERT" issued by J&J, to inform physicians of the profit per vial, per week, per month for administering Procrit.[35] Another document describes a J&J representative's account of a meeting with a physician:

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[31] Plaintiffs' Exhibit 221, BMS/AWP/000157423-35 at BMS/AWP/000157426 and BMS/AWP/000157428 referring to margins created by the spread.

[32] Plaintiffs' Exhibit 132, AZ 0021838, a Zeneca internal memorandum from Thomas Chen, October 12, 1995; *see also* AZ 0037018-19 referring to capturing more accounts due to an increase in the discount.

[33] Memo from C. Pelzel, Director for Marketing to L. McLeod, M. Puccie, Cerenex and Hospital Regional Directors, dated of 11/24/93, GSK-MDL-ZN-02-071790-1.

[34] Plaintiffs' Exhibit 20, Zeneca Pharmaceuticals memo from Market Strategy & Contract Operations, November 3, 1995, AZ0237142-63 at AZ0237143.

[35] Plaintiffs' Exhibit 362, MDL-OBI00063642-3.

> "We then began to discuss cost. I was able to pull out my computer and walk him through each health plan and what he might expect for reimbursement. We then went through the Medicare example showing approximately $327 per patient on a 3 vial visit. I then showed a grid showing the possible potential on a single 3 vial patient if the health plan reimburses between AWP-5 to AWP-15%. Dr. Kassan seemed so excited about getting started, I see a tremendous opportunity for all, or most of his patients. We discussed safety issue and infection rates, but they didn't seem to be of issue to him.
>
> "I said that I would have someone deliver the Colorado grid showing the reimbursement rates for each plan along with the provider relations Phone #s. He also liked the Medicare AWP example."[36]

39. All of these documents (and there are many more examples) show the recognition by drug companies of the ability to increase market share using the disparity between AWP and acquisition cost.

IX. ROLE OF PUBLISHERS

40. Let me explain how AWP is transmitted to the marketplace.

41. The AWP is established by the manufacturers either directly or indirectly. In the direct approach, a manufacturer sends an AWP or suggested AWP to a publisher.[37] Those AWPs are then published by the publisher, either with modification or without. Discovery materials suggest that the manufacturers expressly or tacitly approved the AWPs by sending them out to providers[38]

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[36] *See* Plaintiffs' Exhibit 272, MDL-CEN00090283-302.

[37] *See* Plaintiffs' Exhibit 17 (An AZ email from John Freeberry, November 30, 2001, which states "Up until the last year or so manufacturers basically decided what the AWP should be – in other words they recommended a spread over the WAC (catalog) price which results in the Average Wholesale price (AWP)."); Plaintiffs' Exhibit 22, contains a listing of drugs sent to First DataBank by AZ, which includes a suggested AWP column; and Plaintiffs' Exhibits 237, 238, 239, and 360 (Ortho Biotech (J&J Group) letters to MediSpan and First DataBank indicating new AWPs).

[38] *See*, for example, BMS Response to Interrogatory 5, January 19, 2004 (Plaintiffs' Exhibit 178) which states: "Generally speaking, there is a multi-step information flow between BMS and the above publications [Red Book, First DataBank, and MediSpan]. In 'Step 1,' someone from the finance department within BMS sends to the 'Pricing Administration' department either a price on a new drug or a price increase on an existing drug … In 'Step 2,' Pricing Administration inputs the information into the BMS internal computer system. In 'Step 3' customers are notified of the new prices. … In 'Step 4' the publications are notified. … In 'Step 5' the publication generally sends

42. Other companies, like BMS, send to the publisher another form of list price (WLP), from which the publisher derives AWP using a known formula.[39] For example, according to a BMS document, BMS instructed the publishers to use a 25% mark-up factor for BMS oncology products: "Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%." The Red Book made this change as BMS directed.[40]

43. Either by submission of AWP or by submission of a number from which AWP is derived, all manufacturers control AWP.

X. ANALYSIS OF DEFENDANTS' DATA SUGGESTS AWP INFLATION WAS UNDERTAKEN FOR COMPETITIVE GAIN

44. Further support for the theory that the Defendants recognized the importance of the spread and manipulated it for their competitive purposes emerges from analysis of Defendants' invoice data. In the section below, I examine departures of Defendants' AWPs from the associated ASPs. I also show changes in spreads following events that altered the competitive environment. These changes provide "natural experiments" in which to examine the use of the spread as a competitive strategy. Event studies such as these are widely used in empirical economics to test theories and estimate policy effects.[41]

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a 'report' back to BMS demonstrating what it has done with the information BMS has provided. Such reports usually show the WLP/DLP and AWP."

[39] See Plaintiffs' Exhibit 178 described above; Plaintiffs' Exhibit 179, a series of BMS letters to the publishers; Deposition of Denise M. Kaszuba (Associate Manager of Pricing Support for BMS), *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS, August 18, 2005, at p. 44; and Plaintiffs' Exhibit 184 (Affidavit of Denise M. Kaszuba).

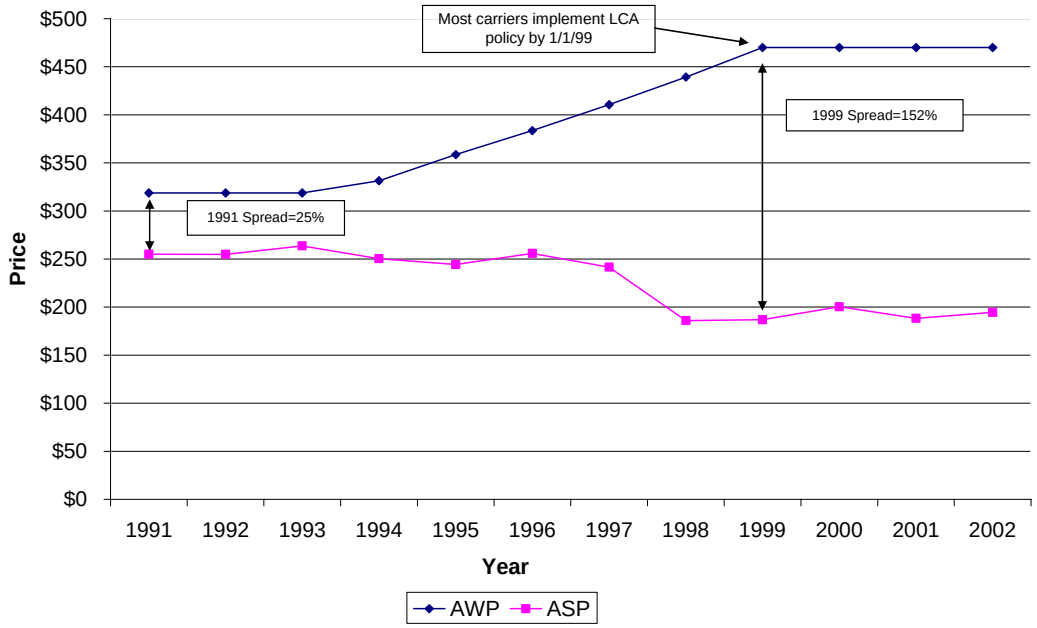
[40] *See* Plaintiffs' Exhibits 183, letters to MediSpan and First DataBank requesting this increase (BMSAWP0011245-48) and Plaintiffs' Exhibit 184 (Affidavit of Denise M. Kaszuba, ¶ 3).

[41] A. Craig MacKinlay, "Event Studies in Economics and Finance," *Journal of Economic Literature*, Vol. 35, 1997, pp. 13-39.

45. For one example, let me turn again to the AstraZeneca drug, Zoladex. As noted earlier, Zoladex is a treatment for prostate cancer. During the Class Period, the principal competitor to Zoladex was Lupron, a drug that the courts have found was promoted using spread manipulation among other devices.[42] In the chart below, I compare the trends in the Average Sales Price (ASP), which is a measure of the acquisition cost to physicians, and the AWP.

46. Furthermore, in Federal litigation, AstraZeneca has pled guilty to providing Zoladex free samples to physicians who were encouraged to submit those free samples for reimbursement.[43] AstraZeneca also used "return-to-practice" (i.e., spreads) to market Zoladex to physicians.[44]

Zoladex Annual AWP vs. ASP, 1991-2002 (NDC 000310096036)



[42] *See* Sentencing Memorandum of the United States, *United States of America v. TAP Pharmaceutical Products, Inc.*, Criminal Action No. 01-CR-10354-WGY.

[43] *See* Plaintiffs' Exhibits 1-5, 12. *United States of America v. AstraZeneca Pharmaceuticals LP*, Criminal Action No. 03-55-JJF, Proceedings, June 20, 2003 and *United States of America v. Robert A. Berkman*, Criminal Action No. 03-45-JJF, Proceedings, July 17, 2003.

[44] *Ibid.*

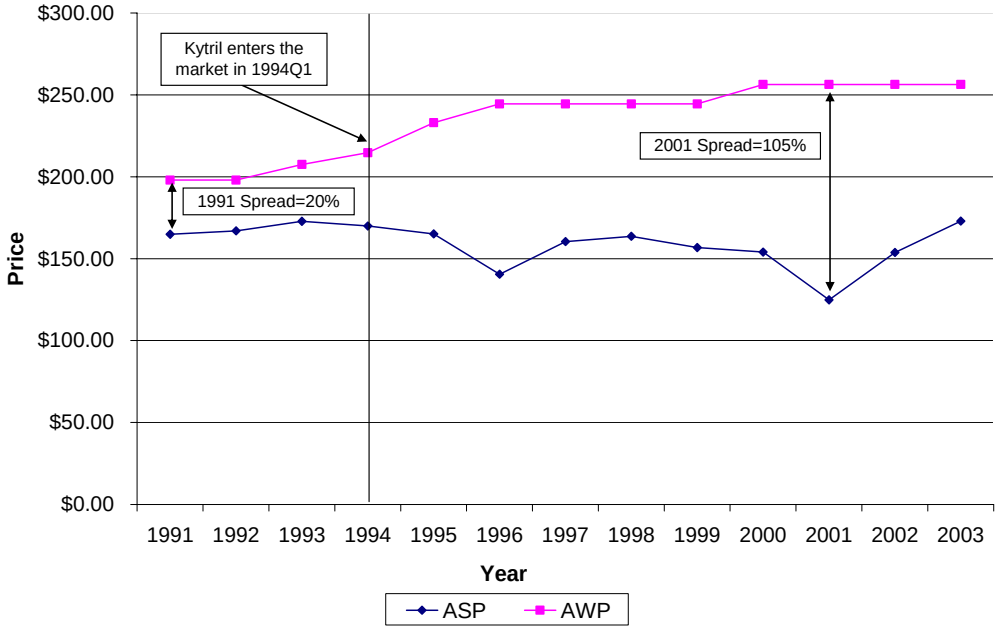
47. The chart demonstrates several important points. First, through 1994, the ASP and AWP of Zoladex tracked one another fairly closely. Beginning in 1995, however, two things occurred. The ASP for Zoladex began to decline, and at the same time, the AWP was raised. That is, the spread was being increased not just because the transaction price was falling but because of an intentional effort to increase the AWP. It is also noteworthy that the increase in the AWP for Zoladex ends in 1999. At that point in time, the majority of Medicare Part B carriers had implemented a Least Costly Alternative (LCA) policy whereby claims for Lupron and Zoladex would be reimbursed based on the AWP for the less costly of the two (which was and still is Zoladex).[45] This meant that any increase in Zoladex's AWP would increase the spread for both Lupron and Zoladex and thus the competitive impetus for AWP manipulation was largely removed.

48. Another example of data illustrating the use of AWP inflation for competitive purposes can be found by examining the ASP and AWP trends for the anti-emetic drug, Zofran. During the 1990s, Zofran was in competition with another injectable anti-emetic, Kytril, manufactured by SmithKline.[46] In 2000 Glaxo and SmithKline merged, at which time Kytril was divested from the newly formed company, GlaxoSmithKline. The figure below shows how AWP inflation was used as a competitive response by Glaxo to the entry of Kytril into the market.

[45] The LCA policy was adopted by HCFA carriers beginning in May 1997 with South Carolina and was ultimately used by almost all states.

[46] GSK's drugs Kytril and Zofran were previously among the Track 1 covered drugs. I understand that GSK has settled with Plaintiffs. Nonetheless, the data provide a useful illustration of the economics of spread manipulation.

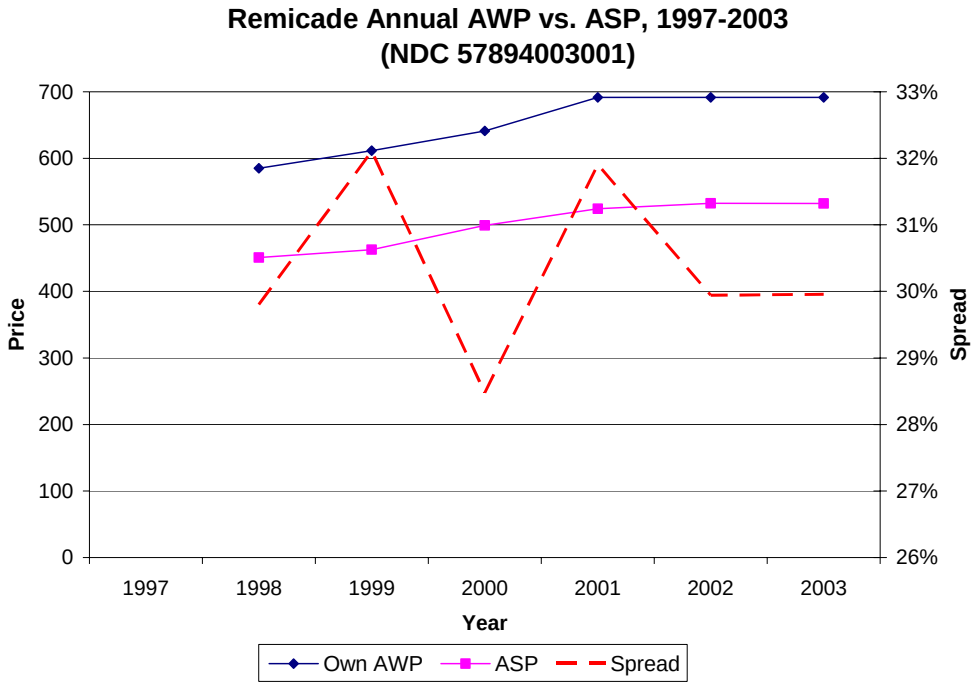
Zofran Annual ASP vs. AWP, 1991-2003 (NDC 00173044200)



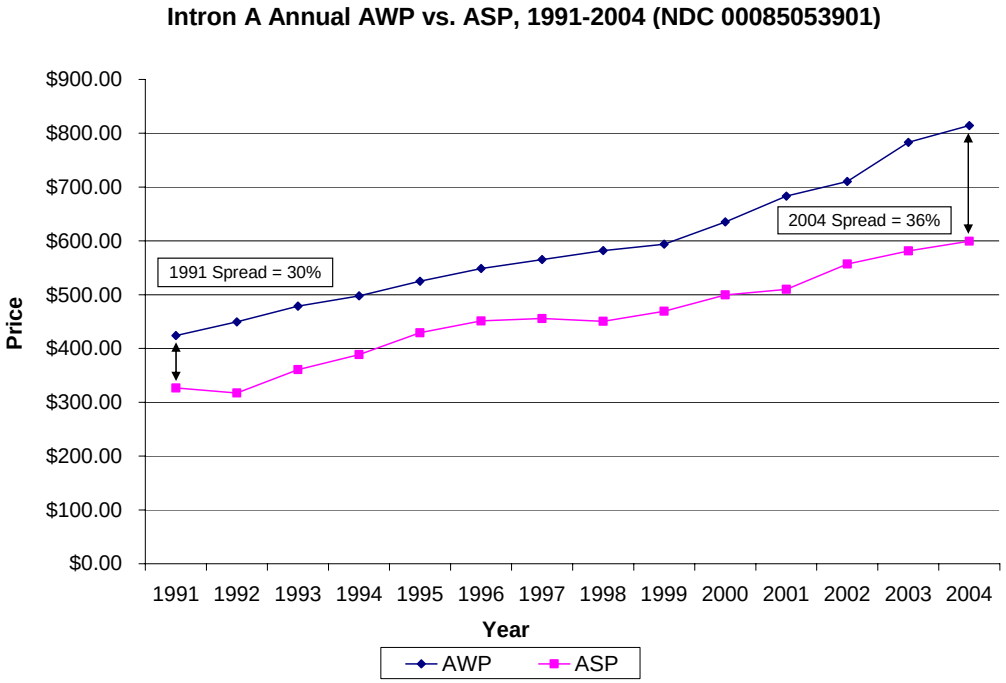
49. Prior to the entry of Kytril, the ASP and AWP of Zofran track almost perfectly, with a 20% spread between them. Thereafter, the AWP of Zofran continues to climb, while the transaction price declines, leading to much larger spreads. As in the case of Zoladex, it cannot be argued here that the manufacturer simply neglected to alter the published AWP to reflect increasingly generous discounts but instead that AWPs were being pushed upwards at the same time as the ASP was falling. Numerous memoranda and other communications obtained from GSK document the explicit and conscious nature of the competition between Zofran and Kytril based on inflating their respective AWPs.[47]

50. For Remicade, a J&J drug, the average spreads over the Damage Period were approximately 30 percent. These spreads created margins for providers and meant that the AWP was not representative of the real average price Remicade.

[47] *See*, for example, GSK-MDL-KY01-005532-36, GSK-MDL-ZN02-072192, GSK-MDL-ZN-06-007997, GSK-MDL-ZN-02-071651 and GSK-MDL-ZN-02-071790-1.

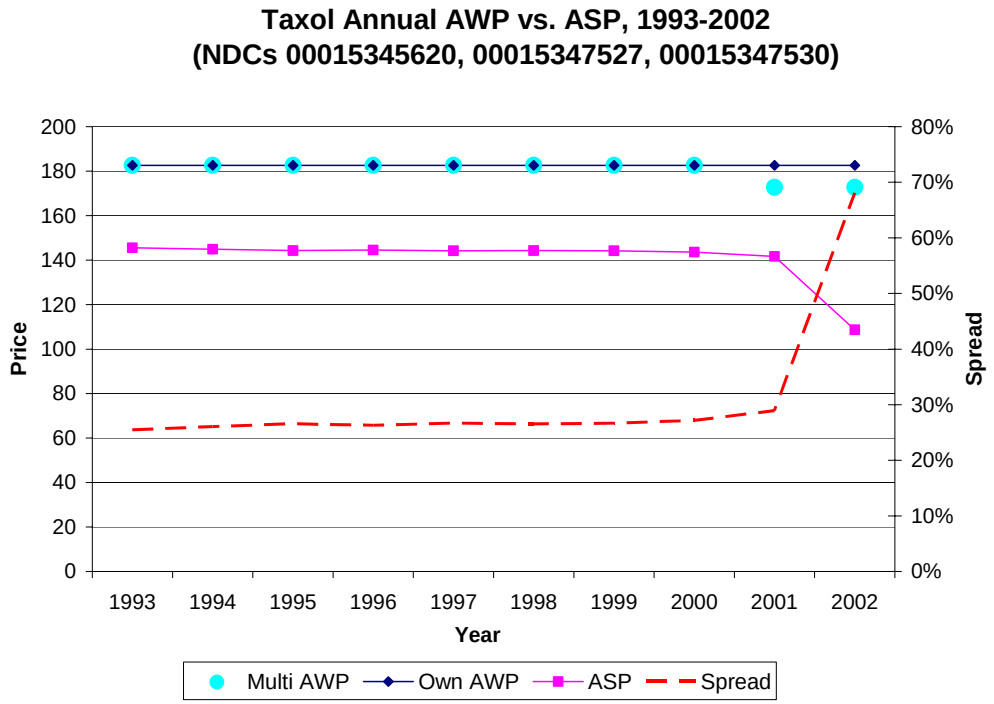


51. Another example, using Defendants' data, illustrates the progression of spreads over time. The chart below shows the increase over time in both the AWP and the spread for one NDC of the Schering-Plough drug, Intron A. For Intron A, the spread increased from 30% in 1991 to a high of 36% in 2004. Again, the data show that the actual acquisition cost to providers was consistently lower than the published AWP.



52. Another example of the use of spread for economic and competitive motivation arises from data involving BMS' Taxol.[48]

[48] Three NDCs for the 30 mg presentation of Taxol (00015345620, 00015347527 and 00015347530) were appended together in order to obtain a complete series of data from 1993 to 2002.



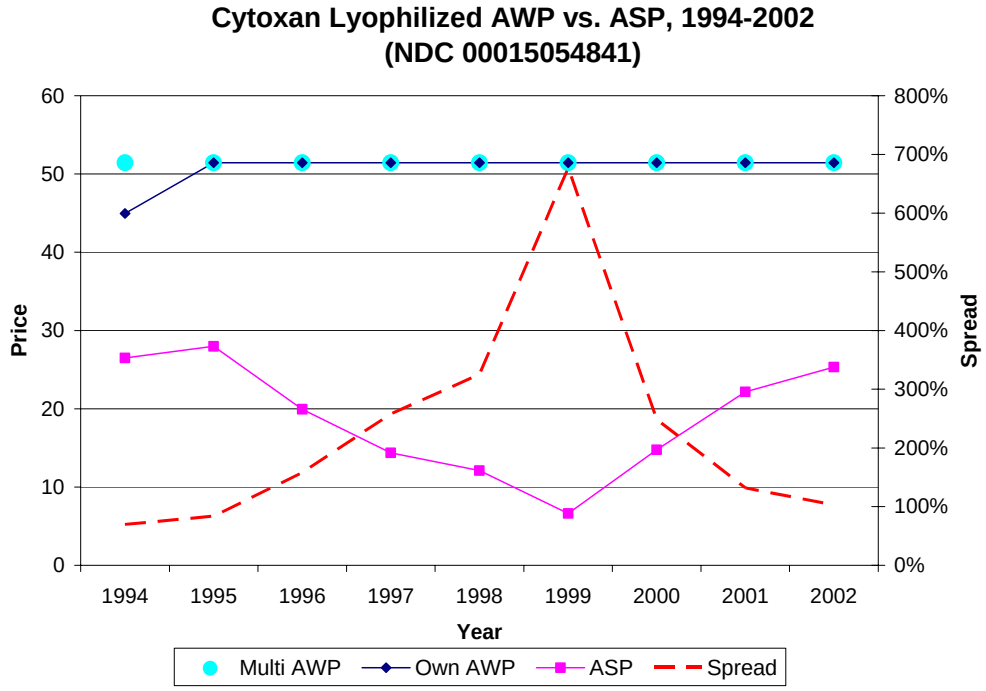
53. Taxol enjoyed patent protection until losing exclusivity in late 2000, after which the licensed brand-name drug Onxol entered the market, followed by generic versions of paclitaxel in 2001. Up until this point, the WLP and AWP for Taxol had generally remained constant over time, and BMS generally did not use contract pricing for Taxol that was lower than list price.[49] But in response to generic competition, BMS lowered the contract prices paid by physicians, without changing the WLP and AWP.[50] As the data reveal, confidential contract prices for Taxol fell throughout 2001 and 2002 as the unit weighted average spread across all NDCs increased 84 percentage points between 2001 and 2002. A BMS witness confirmed that this pricing strategy eventually succeeded in stemming Taxol's market share erosion.[51]

54. The AWP and ASP for BMS' Cytoxan are set forth below.

[49] *See* Deposition of Christof A. Marre, August 26, 2005, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS ("*Marre Deposition*") at pp. 40-41, 100-01.

[50] *Ibid.*, at pp. 100-01.

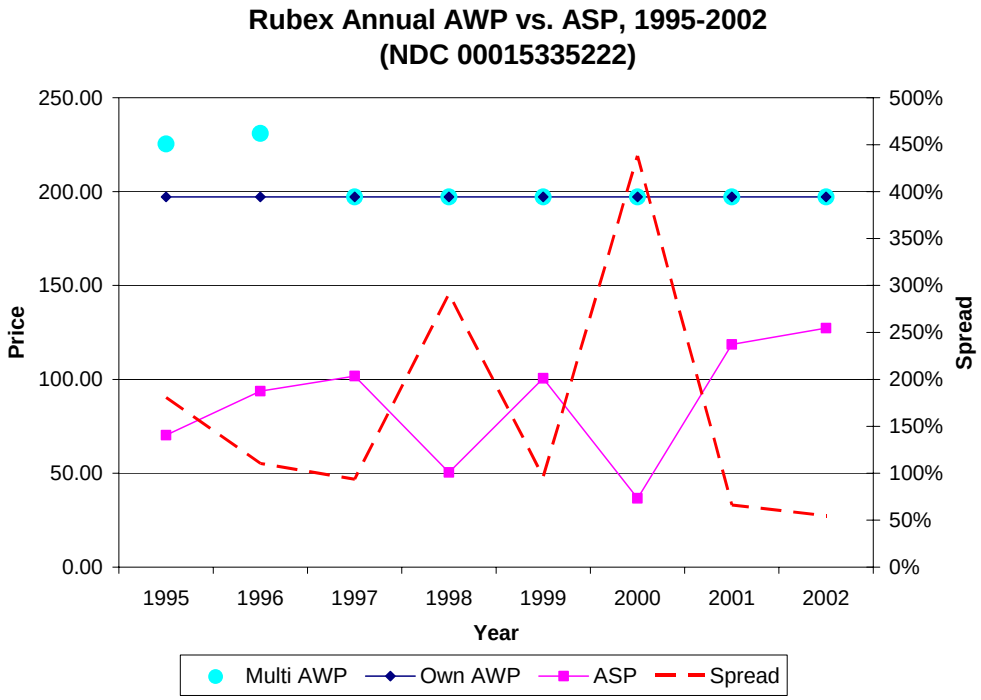
[51] *Ibid.*, at p. 107.



55. As the data reflects, BMS kept the WLP and hence the AWP constant for Cytoxan, while already large spreads in 1997 continued to grow over time. In other words BMS was offering substantial discounts on Cytoxan. These discounts were not included in calculating WLP and hence the AWP was substantially inflated. According to deposition testimony, BMS also recognized that generic manufacturers were having trouble manufacturing the lyophilized version of Cytoxan and began to exit the market. Apparently in response, BMS increased some contract prices, thus explaining the increase in ASP from 1999 to 2002 above.[52]

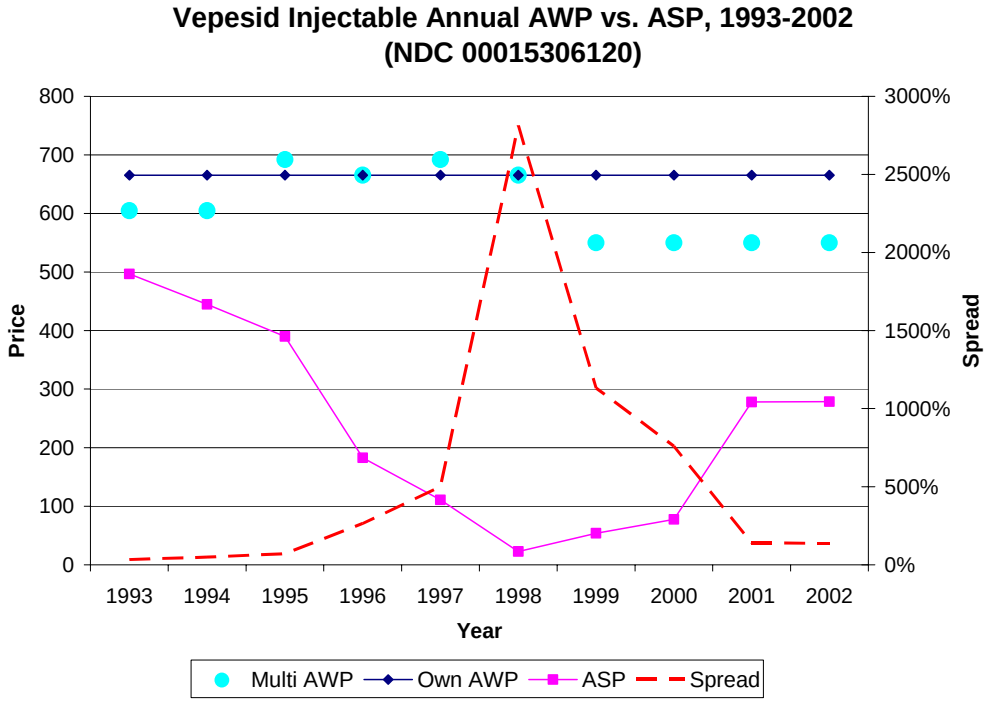
56. Rubex is another BMS drug used to treat cancer. The spread information for Rubex is set forth below.

[52] *Ibid.*, at pp. 88-90.



57. As can be seen, the spread for Rubex exceeded 400% in 2000, as BMS apparently implemented a discounting strategy and the WLP (and AWP) far exceeded average acquisition costs.

58. The spread information for Vepesid is set forth below.

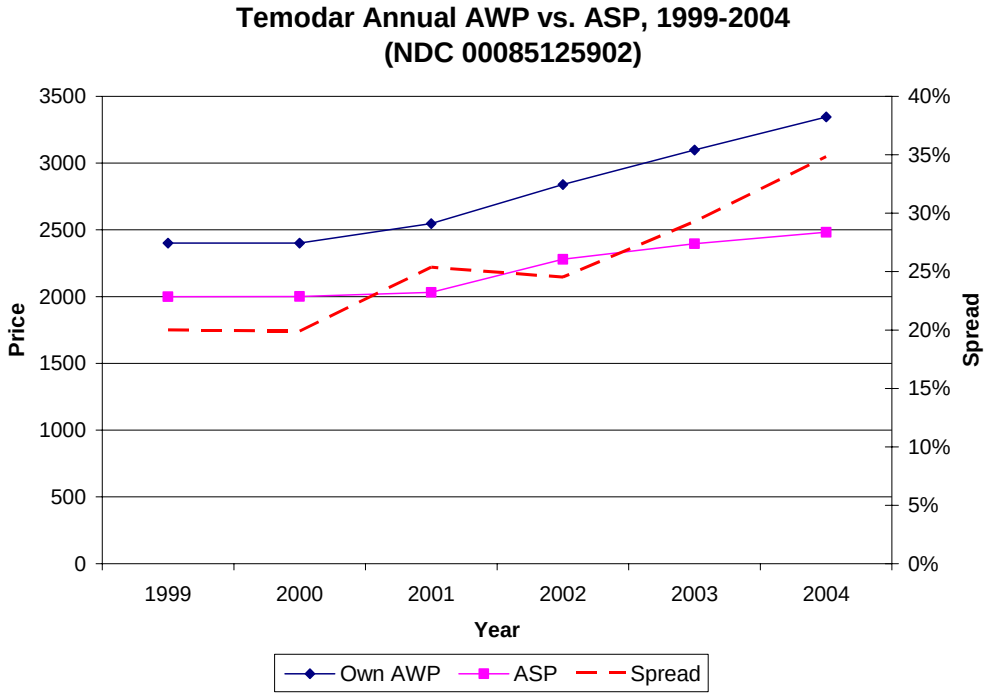


59. Vepesid is the BMS brand name for etoposide, a chemotherapy agent with several generic competitors. The AWP remained relatively constant but the product was sold to providers at heavily discounted prices throughout the late 1990s and 2000.[53] A BMS witness testified that most Vepesid sales were made using discounted contract pricing which means that few physicians bought at WLP.[54]

60. Temodar is a Schering Plough product and another agent used to treat cancer.

[53] This pricing pattern, with the lowest pricing in the late 1990s followed by an increase, is explained by Mr. Marre from BMS, who states that "[w]ith VePesid we had a problem in that the price had deteriorated very massively compared to other generic drugs. So, I recall that we weren't always willing to continue matching those low prices. It was already so low" (*Marre Deposition* at p. 94).

[54] *Ibid.*, at pp. 130-31.



61. Temodar's AWP increases in each year between 2000 and 2004 at a rate that exceeds the increase in its ASP. As a consequence the annual average spread for Temodar grows from approximately 20% in 1999 to 35% in 2004.

62. In summary, examination of the patterns of the list (AWP) and transaction (ASP) prices over time found in Defendants' data provides strong support for the theory that AWP inflation was a deliberate competitive strategy. In particular, many AWPs consistently increased over the period or remained constant, even while ASPs were flat or decreasing.

XI. PAYER KNOWLEDGE OF AWP INFLATION

63. In the context of Class 3, Defendants' experts have raised the question of whether third-party payers would have been differentially affected by the alleged AWP inflation because of differences in knowledge about the relationship between AWP and ASP (*i.e.*, acquisition cost).

64. In part, I address this question in the section on why provider competition fails to mitigate the impact of AWP inflation. Because the issue of variation in payer expectations has been noted as a particular concern by the Court,[55] however, it deserves further comment here.

65. In addition to the arguments I offered in Section VII, Professor Berndt, in his report and in his academic publications, suggests several reasons why payer knowledge would not have dissipated the impact of the AWP inflation. First, is the notion of "the importance of being unimportant." This concept, originally used by Marshall to explain low price responsiveness of demand for some products, refers here to the fact that payers focus their cost control efforts on services that represent a large share of the overall health benefit.[56] During the Class Period, specialty pharmaceuticals represented no more than 1-2% of private health insurance spending and thus would not have been the subject of much analysis by payers.[57] Moreover, the drugs involved in this litigation represent a tiny percentage of the thousands of pharmaceutical products available in the U.S. market.

66. Given the large number of drugs and services that third-party payers reimburse, there is also a need to rely on a common standard to process literally millions of transactions. Ascertaining the acquisition cost for each and every drug would simply not be feasible for payers. Moreover, because many of the rebates and discounts to providers would not be reported in standard transaction data such as is summarized by IMS Health and other data services, payers could not easily obtain even average acquisition cost information from third-party sources. In this context, the published AWPs, which are readily available to payers from sources such as the

[55] *Memorandum and Order*, e.g., p. 66.

[56] E.R. Berndt, "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs* 20(2):100-114, 2001.

[57] *Berndt Report*, Section V, pp. 98-99.

Red Book, MediSpan, and First Databank, provide what Berndt calls a "focal point" for reimbursement.[58]

> "Moreover, since AWP was publicly known, it served as a convenient focal point metric for contractually specifying various reimbursements, and for efficiently adjudicating pharmacy transactions electronically."[59]

67. Finally, it is possible to put bounds on the importance of variation in payer knowledge of the spread, using Dr. Hartman's "revealed preference" approach (*i.e.*, that the variation in payer beliefs about the relationship between AWP and ASP should be reflected in negotiated reimbursement rates). According to the MedPAC report, "most plans use an AWP pricing formula that is in the range of 90 to 100 percent of AWP." By comparison, the spreads that Dr. Hartman's analysis has revealed are in many cases on the order of 100% or more. Under those circumstances, all private third-party payer Class members (Class 3) would have been substantially overcharged and by the same mechanism. Moreover, relative to the magnitude of AWP inflation, the magnitude of variation in payer expectations of the spread, as revealed by the observed reimbursement formulae, is small.

XII. PAYORS' KNOWLEDGE AS TO SPREADS AND SPREAD MARKETING SCHEMES

68. With respect to Class members' knowledge, it is widely known that due to competitive concerns, pharmaceutical companies regard the prices actually offered to purchasers to be confidential. For its part, BMS put all forms of discounts, including discounted pricing, in confidential contracts with physicians, hospitals, and buying groups; these confidential discounts

[58] *Ibid.*, Sections II.B., p. 11 and III.A., p. 17.

[59] *Ibid.*, Section III.A., p. 17.

would not be reflected in the WLPs of BMS drugs.[60] Many of the contracts that reflect the discounts with providers are marked confidential.[61]

69. I have also not seen the "Return to Practice" type of documents used by certain of Defendants to market their products reported in the public record or in the peer-reviewed literature. The type of pricing secrecy or lack of transparency common to this industry, aided by the lack of disclosure noted above, supports the notion that third-party payers were not aware of the spreads or spread marketing practice I have referred to in this report.

XIII. SUMMARY AND CONCLUSIONS

70. AWP is the most widely used pricing benchmark in the industry. During the Class Period, AWP or a discount off of AWP was the basis for Medicare reimbursement for brand name drugs covered under Part B. Likewise, multi-source drugs were reimbursed under Medicare based on the median AWP for generic versions or the lowest brand-name AWP. Most private insurers have followed Medicare's lead and also reimburse for physician-administered drugs using a discount off of AWP.

71. The system of third-party reimbursement and the large number of drugs, procedures, and other services covered by health insurers combined with the opaque discounting practices of the Defendants presented an opportunity for the alleged fraud to have occurred.

72. Physicians and other providers of the drugs at issue in this matter could increase their net revenues (*i.e.*, reimbursement net of the acquisition costs of the drugs) under this system

[60] *Marre Deposition* at pp. 78-84.

[61] *See* MDL-OBI00054909-13 (1992 Ortho Biotech contract with Caremark, ¶ 7); MDL-OBI00055078-82 (1993 Ortho Biotech Inc. contract with Stadtlanders, ¶ 7); AZ0431262-71 (AZ form Urology Practice contract, ¶ 6 which states "Urology Practice and Participating Physicians shall keep confidential all of the terms and conditions of this Agreement, and the existence of this Agreement, throughout the duration hereof and for a period of three (3) years following the effective date of expiration or termination."); WAR0043141-48 (1995 Warrick contract with Fallon Clinic Pharmacy requiring "confidentiality of all pricing, marketing or other Warrick product information, including this agreement" during term of contract and three years afterward at WAR0043146).

by selecting drugs with larger spreads – *i.e.*, drugs where the AWP was relatively inflated in comparison to the acquisition cost of the drug.

73. Manufacturers, in turn, could increase their unit sales not only by discounting their products, but also by raising or maintaining their reported AWPs. Moreover, raising or maintaining the AWP would be a highly profitable strategy in that it could be expected to increase the number of units sold, but would have no negative impact on the manufacturers' profit margins.

74. Analysis of Defendants' data suggests that spreads for Defendants' products were substantial and in many cases increasing over the Class Period. Moreover, analysis of several natural experiments in which the competitive environment for a Class drug was altered support the theory that AWP inflation was a competitive strategy.

75. Finally, because their payments to providers for the AWPIDs were a mathematical function of the AWPs, members of the three Classes would have been economically injured if the Defendants inflated those AWPs as alleged. That is, members of the Classes paid more for these drugs than they would have in the absence of the alleged fraud.

76. To arrive at these opinions, I have appealed to theory, data, and methods generally relied upon by experts in my field and I have appropriately applied standard approaches and analysis.

I declare that the foregoing is true and correct under penalty of perjury.

Meredith Rosenthal, Ph.D.

10/27/06 Cambridge MA
Date and Place of Execution

Attachment A

Curriculum Vitae

CURRICULUM VITAE

October, 2006

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Boston, MA 02115
(617) 432-3418

DATE & PLACE OF BIRTH:

5/7/68	Boston, MA

EDUCATION:

1998	Health Policy (Economics track), Ph.D., Harvard University
1990	International Relations, A.B., Brown University

ACADEMIC APPOINTMENTS

1998-2006	Assistant Professor of Health Economics and Policy
2006-	Associate Professor of Health Economics and Policy Department of Health Policy and Management Harvard School of Public Health

OTHER PROFESSIONAL EXPERIENCE:

1993-1994	Analyst, Health Economics Research, Inc./The Center for Health Economics Research
1990-1993	Consultant, Price Waterhouse, Tax Economics Department

PROFESSIONAL SOCIETIES:

1995-present	Member: AcademyHealth, American Public Health Association, International Health Economics Association

PUBLIC SERVICE

2001	Chair, Massachusetts Special Commission on Physician Compensation
2003	Expert Testimony, Senate Special Committee on Aging, Hearing on Direct to Consumer Advertising of Prescription Drugs: Exploring the Consequences
2005	Expert Testimony, House Committee on Education and Workforce, House Subcommittee on Employer-Employee Relations, Hearing on Examining Pay-for-Performance Measures and Other Trends in Employer-Sponsored Health Care

AWARDS

2003	Labelle Lectureship in Health Policy, McMaster University
2006	Alfred P. Sloan Foundation Industry Studies Fellowship

MAJOR ADMINISTRATIVE RESPONSIBILITIES:

2000-present	Committee on Higher Degrees in Health Policy, Harvard University
1998-present	Admissions Committee, Ph.D. Program in Health Policy, Harvard University

EDITORIAL ACTIVITIES:

1997-1998	Assistant Editor, Evidence-based Health Policy and Management
1997-present	Referee: *Journal of Health Economics, Inquiry, Health Services Research, Health Affairs, Journal of the American Medical Association*

MAJOR RESEARCH INTERESTS:
Financial incentives for physicians
Economics of the pharmaceutical industry
Pay-for-performance in health care
Consumer-directed health plans
Behavioral health

TEACHING EXPERIENCE:

1999	Health Policy and Management 507: Mental Health Economics and Policy in the United States
2003-present	Health Policy and Management 209: Economics of Health Policy

TESTIMONY:
In re Lupron Marketing and Sales Practices Litigation, United States District Court, District of Massachusetts, MDL No. 1430, CA No. 01-CV-10861.

In re Pharmaceutical Industry Average Wholesale Price Litigation, United States District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS

In re Neurontin Marketing and Sales Practices Litigation, MDL No. 1629, Master File No. 04-10981, United States District Court, District of Massachusetts.

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Attachment B

Documents Relied Upon

Bates-Numbered Documents:

- AZ 0021838
- AZ 0037018-19
- AZ0431262-71
- BMS 000157428
- BMS AWP 000157426
- BMS AWP 0011221
- GSK-MDL-KY01-005532-36
- GSK-MDL-ZN-02-071651
- GSK-MDL-ZN-02-071790-91
- GSK-MDL-ZN02-072192
- GSK-MDL-ZN-06-007997
- MDL-OBI00054909-13
- MDL-OBI00055078-82
- WAR0043141-48

Plaintiffs' Exhibits: 1, 2, 3, 4, 5, 12, 14, 15, 17, 20, 22, 132, 178, 179, 183, 184, 206, 221, 237, 238, 239, 272, 360, 362, 367.

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